Department of Energy
Washington, DC 20585

SAFETY EVALUATION REPORT

for the Pu OXIDE AND Am OXIDE SHIPPING CASK

Docket 06-18-5320

Prepared by: James M. Shuler Date: 3/1/6
James M. Shuler
Health Physicist
Office of Licensing, EM-24

Approved by: Date: 3/3/06
Mark A. Gilbertson
Headquarters Certifying Official
Deputy Assistant Secretary for
Environmental Cleanup and Acceleration
Office of Environmental Management

Safety Evaluation Report
for the
Safety Analysis Report-Packages (SARP), Pu Oxide and Am Oxide Shipping Cask, DPSPU 79-124-1, Rev. 1

Docket 06-18-5320

February 24, 2006

INTRODUCTION

The Idaho National Laboratory (INL) has prepared for the U.S. Department of Energy (DOE) revisions to the Safety Analysis Report for Packaging (SARP) and Supplement 1 to the SARP[1] for the 5320 Package (referred to herein as the *5320 SARP*). The 5320 Packaging is a Type B( )F packaging system designed for shipping up to approximately 0.2 kW of heat source plutonium (primarily ^{238}Pu) or Americium, in various chemical forms and mechanical configurations.

This Safety Evaluation Report (SER) documents the review performed by the Lawrence Livermore National Laboratory (LLNL) staff, at the request of DOE, of the 5320 SARP, Revision 1. Revision 1 addresses the transfer of responsibility to INL for the use, inspection, maintenance, repair, modification, handling, shipping, storage and cleaning of the 5320 Package, described in Chapter 9, Quality Assurance.

This design is being approved under the B( )F requirements. To clearly state the restrictions on the use of this design, the following statement has been added to CoC as pargraph 5.(c)(4): *Because this design is a B( )F it may be used with the following additional conditions: (a) packagings fabricated after August 31, 1986 are not authorized for use; (b) a serial number that uniquely identifies each packaging which conforms to the approved design, is assigned to and legibly and durably marked on, the outside of each packaging; and (c) use of these packagings in commerce expire on October 1, 2008.*

The review findings detailed below only involve SARP Chapter 9. Thus, discussion of SARP Chapters 1, 2, 3, 4, 5, 6, 7 and 8 have been omitted.

Chapter 9: Quality Assurance

Revisions 1 of the 5320 SARP describes the applicant's (Idaho National Laboratory [INL]) quality assurance (QA) program for design, procurement, fabrication, handling, shipping, storage, cleaning, assembly, operation, inspection, testing, maintenance, repair, modification, and use of the 5320 Package.

The QA review verifies that the applicant's QA program described in Chapter 9 in submittals of Revision 1 of the 5320 SARP meets the regulatory requirements of 10 CFR 71 Subparts D, F, G, and H listed in Section 9.2 below.

9.1 Elements Reviewed

The following elements of the applicant's QA program were reviewed. Details of the review are provided in Section 9.3 below.

9.1.1 Description of Applicant's QA Program

- Scope
- QA Program Documentation and Approval
- Summary of 18 Quality Assurance requirements of 10 CFR 71, Subpart H.
- Cross-Referencing Matrix of 10 CFR 71, Subpart H to the Applicant's

QA Program/Procedures

9.1.2 Applicant's QA Requirements

- Graded Approach for Structures, Systems, and Components Important to Safety
- Applicant's QA Criteria and Package Activities

9.2 Regulatory Requirements

10 CFR 71 requirements applicable to the QA review are as follows:

- The applicant must describe the quality assurance program for the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the package. [§71.31(a)(3), §71.37]
- The applicant must identify established codes and standards proposed for the package design, fabrication, assembly, testing, maintenance, and use. In the absence of any codes and standards, the application must describe the basis and rationale used to formulate the package quality assurance program. [§71.31(c)]
- Package activities must be in compliance with the quality assurance requirements of Subpart H (§71.101-§71.137). A graded approach is acceptable. [§71.81, §71.101(b)]
- Sufficient written records must be maintained to furnish evidence of the quality of the packaging. These records include results of the determinations required by §71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of maintenance, modification, and repair activities; and other information identified in §71.91(c). Records must be retained for three years after the life of the packaging. [§71.91(c)]
- Records identified in §71.91(a) must be retained for three years after shipment of radioactive material. [§71.91(a)]
- Records must be available for inspection. Records are valid only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. [§71.91(b)]
- Any significant reduction in the effectiveness of a packaging during use must be reported to the certifying authority. [§71.95(a)]
- Details of any defects with safety significance in a package after first use, with the means employed to repair the defects and prevent their reoccurrence, must be reported. [§71.95(b)]
- Instances in which a shipment does not comply with the conditions of approval in the certificate of compliance must be reported to the certifying authority. [§71.95(c)]

9.3 Review Procedures

This section details the review of the elements listed in Section 9.1 of this TRR.

9.3.1 Description of Applicant's QA Program

9.3.1.1 Purpose and Scope

The Purpose and Scope of Chapter 9, Quality Assurance, of the SARP were reviewed to confirm that Chapter 9 explicitly states the applicant's QA Program complies with 10 CFR 71, Subpart H, and is applied to package-related activities including procurement activities consistent with the applicable regulatory requirements. Idaho National laboratory became responsible for the 5320 packaging in February 2005 at which time Argonne National Laboratory –West (ANL-W) became part of INL. Section 9.0 states that Chapter 9 discusses the INL QA requirements for the design, fabrication, assembly, acceptance testing, procurement, use, periodic inspection, weld examination, maintenance, repair, modification, handling, shipping, storage, and cleaning of the 5320 package that comply with 10 CFR 71, Subpart H. Section 9.0 further explains that per the approval of DOE-NE, INL will continue to use the previous ANL-W QA program, procedures, and documents listed in the Chapter 9 reference list. Section 9.2.1 states that INL is in the process of replacing the previous ANL-W procedures (AWPs) with INL laboratory wide procedures (LWPs).

Section 9.1 and Figure 9-1 of the SARP describe the applicant's organization, including the QA groups and their responsibilities relative to management and implementation the QA Program. The applicant purchases 5320 Package fabrication services from suppliers that have been evaluated and approved to meet the applicable requirements of 10 CFR 71, Subpart H.

9.3.1.2 Program Documentation and Approval

Section 9.0 of the SARP states that INL will use the previous ANL-W QA Program (QAP), W0001-0929-QM, Revision 10, that describes the overall framework within which the INL quality assurance activities for the 5320 Package are implemented. Section 9.2 describes that the ANL-W QAP, referred to as the INL QAP, meets the requirements of 10 CFR 830.120,[2] DOE Order 414.1B,[3] and the provisions of NQA-1-2000.[4]

Quality assurance activities for the 5320 Package operate within the scope of the previous ANL-W Radioisotope Power System/Heat Source (RPS/HS) QA Program Plan (QAPP) that is referred to as the INL RPS/HS QAPP. The INL RPS/HS QAPP is implemented with the use of procedures that detail specific requirements in the INL QAP. Section 9.0 explains that per the approval of DOE-NE, INL will continue to use the previous ANL-W QA program, procedures, and documents listed in the Chapter 9 reference list that are in the process of being replaced with equivalent INL LWPs. Section 9.19 lists the current QA implementing procedures that consist of a combination of the previous ANL-W AWPs and new INL LWPs.

As required by §71.31(a)(3) and §71.37, Sections 9.1.1 and 9.2 of the SARP identify that the INL-W RPS/HS QAPP complies with 10 CFR 71, Subpart H (in addition to the INL-W QAP, DOE Order 460.2A,[5] DOE Order 460.1B,[6] and NQA-1-2000[4]). Idaho National Laboratory purchases 9516 Package fabrication services from suppliers that have been evaluated and approved to meet the applicable requirements of 10 CFR 71, Subpart H. Idaho National Laboratory uses NQA-1-2000 as a quality management standard for meeting the requirements of 10 CFR 71, Subpart H.

Additional information on the hierarchy and relationship of requirements documents and the relevant INL QA plans and implementing procedures is provided in Figure 9-2. The current revision and date of the applicable INL QA Plans are provided in the References section in Chapter 9.

9.3.1.3 Summary of 18 Quality Assurance Requirements from 10 CFR 71, Subpart H

Table 9-1 lists and summarizes the INL-W RPS/HS QAPP sections that implement the 18 quality assurance requirements in 10 CFR 71, Subpart H.

9.3.1.4 Cross-Referencing Matrix

Table 9-1 provides a cross-referencing matrix that links the INL-W RPS/HS QAPP sections to the corresponding QA requirements in 10 CFR 71, Subpart H.

9.3.2 Applicant QA Requirements

9.3.2.1 Graded Approach for Structures, Systems, and Components Important to Safety

Section 9.2.3 was reviewed to verify it describes the graded application of the ANL-W RPS/HS QAPP to the 5320 Package structures, systems, and components (SSCs), including software that is important to safety, consistent with the requirements in §71.81 and §71.101(b), and the guidance in Reg. Guide 7.10.[7] Safety-related "Q" package components are categorized as Levels A, B, or C, with Level A items having the largest impact on safety. Table 9-4 of the SARP identifies the graded level of QA controls that apply to each of the INL QA Levels. The 9516 Package SSCs and their QA levels are provided in Table 9-2. Table 9-3 correlates the INL QA Levels A, B, and C for the 9516 Package to the corresponding safety designations in Regulatory Guide 7.10.

The review verified the SSCs listed in Table 9-2 are consistent with information presented in the packaging drawings. The INL QA Levels assigned to the SSCs are properly justified based on their definition, the package type, and the safety function of each SSC.

Section 9.2.3 also explains that all software is to be assessed for and receive the appropriate amount of QA per the graded approach described in Section 4.0 of AWP 4.2. Commercial grade hardware and software can be dedicated (i.e., qualified) for safety-related applications in accordance with the controls described in AWP 2.9, Software Design Control which references AWP 4.9, Software QA.

9.3.2.2 Applicant's QA Criteria and Package Activities

Chapter 9 of the SARP was reviewed to verify it adequately described the QA controls and their application consistent with the requirements in §71.31(a)(3) and §71.37. Chapter 9 describes how the QA controls in each section of the INL-W RPS/HS QAPP (listed in Table 9-1) are applied by INL to the design, procurement, fabrication, handling, shipping, storage, cleaning, assembly, welding, operation, inspection, testing, maintenance, repair, modification, and use of the 5320 Package. Chapter 9 also includes INL's provisions for implementing additional QA requirements of 10 CFR 71 that are listed in Section 9.2 above.

The graded approach described in Section 9.3.2.1 above is used by INL to selectively apply the QA controls to package SSCs and software based on their importance to safety. Each section in Chapter 9 also references the applicable QA implementing procedures that will be used by INL.

Section 9.3 describes the graded design controls for software and hardware. Design modifications to the 5320 Package will be evaluated using the unreviewed safety evaluation process, and will require SARP revisions and approvals by the DOE Office of Nuclear Energy (DOE/NE-50) and DOE Headquarters Packaging Certification Office prior to implementation.

Sections 9.4 and 9.7 collectively identify the graded controls for procurement documents and purchased materials and services including package design, SARP preparation, and packaging fabrication. These provisions ensure that procured items and services affecting quality of the 5320 Package meet appropriate design basis, technical and quality assurance requirements. Procurement documents and changes must be reviewed and approved prior to issue.

Section 9.6 identifies documents that are controlled to ensure correct documents including instructions and procedures (described in Section 9.5) are used and that records requirements are met. Controlled documents include operating procedures (SARP Chapter 7), procurement documents (SARP Section 9.7), and the inspection, testing, and maintenance procedures (SARP Chapter 8 and Section 9.10).

Section 9.9 describes the INL controls for special processes, such as welding of the containment vessels, and nondestructive examination of the package during fabrication, use, and maintenance. ANL-W procedure AWP 2.4 establishes the requirements for qualifying special process procedures, equipment, and personnel in accordance with applicable codes, standards, and specifications.

Sections 9.15 and 9.16 collectively describe the controls for documenting, resolving, and preventing the recurrence of package-related nonconformances identified by package users or suppliers. Section 9.15 includes provisions for obtaining INL Material Review Board approval of nonconformance disposition and reporting package defects that significantly reduce safety performance of the package to the DOE Certifying Authority, in accordance with §71.95.

Section 9.17 summarizes the provisions for ensuring sufficient written records are maintained to furnish evidence of the quality of the 5320 Package. The records and their retention requirements, identified in Section 9.17 and Table 9-5, are consistent with the requirements specified in §71.85, §71.91(a), and §71.91(c).

Section 9.18 describes the INL system for independent assessments that is documented in Section 10 of the RPS/HS QAPP.

9.3.3 Appendix

Chapter 9 in the 5320 SARP includes a list of references and definitions of terms and a list of acronyms commonly used in the Chapter 9.

9.4 Evaluation Findings

9.4.1 Findings

Based on review of the statements and representations in the SARP, the staff concludes that the applicant's quality assurance program has been adequately described and meets the quality assurance requirements specified in 10 CFR 71. The SSCs listed in Table 9-2 are consistent with information presented in the packaging drawings. The applicant's quality assurance program is adequate to assure that the package is designed, fabricated, assembled, tested, used, maintained, modified, and repaired in a manner consistent with its evaluation.

9.4.2 Conditions of Approval

Based on the findings described above, the CoC includes the Chapter 9 requirements, in particular the packaging-specific Quality Assurance requirements.

10.0 References

[1] Safety Analysis Report — Packages (SARP), 5320 Type B package (U), DPSPU 79-124-1, Revision 1, Supplement 1 Revision 1, dated December 18, 1991, amended January 16, 1992.

Supplement to the Safety Analysis Report—Packages (SARP), Pu Oxide and Am Oxide Shipping Cask, DPSPU 79-124-1, Revision 1, Supplement 1, Revision 1, dated December 18, 1991.

[2] *Nuclear Safety Management*, Code of Federal Regulations, Title 10, Part 830.120, Department of Energy, Washington, DC, January 1, 2005.

[3] *Quality Assurance*, DOE Order 414.1B, U.S. Department of Energy, Washington, DC, April 29, 2004.

[4] *Quality Assurance Program Requirements for Nuclear Facilities*, ASME NQA-1-2000, American Society of Mechanical Engineers, New York, NY, June 1, 2001.

[5] *Departmental Materials Transportation and Packaging Management*, DOE Order 460.2A, U.S. Department of Energy, Washington, DC, December 22, 2004.

[6] *Packaging and Transportation Safety*, DOE Order 460.1B, U.S. Department of Energy, Washington, DC, April 2003.

[7] *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Regulatory Guide 7.10, Rev. 1, U.S. Nuclear Regulatory Commission, Washington, DC, June 1986, Rev. 2, U.S. Nuclear Regulatory Commission, Washington, DC, March 2005.